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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

SHANNON COSTA INDIVIDUALLY)	Case No.: 22-cv-5451
AND AS MOTHER, GENERAL GUARDIAN)	
OF L.S., A MINOR,)	COMPLAINT
)	(Jury Trial Demanded)
<i>Plaintiffs,</i>)	
)	
v.)	
)	
CVS PHARMACY, INC.,)	
COSTCO WHOLESALE CORPORATION)	
)	
<i>Defendants.</i>)	

COMPLAINT

Plaintiff Shannon Costa and Plaintiff L.S., pursuant to Fed. R. Civ. P. 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendant CVS Pharmacy, Inc., (hereinafter, “CVS”) and Defendant Costco Wholesale Corporation (hereinafter, “Costco”) (collectively, “Defendants”) and in support state the following:

1. This is an action brought on behalf of Plaintiffs, Shannon Costa (hereinafter, “Plaintiff Mother”), the mother and guardian of L.S. (hereinafter, “Plaintiff Child”), a minor, arising out of the failure of Defendants to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen (hereinafter “APAP”) and its propensity to cause autism spectrum disorder (hereinafter, “ASD”) in children. As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendants entirely failed their duty to adequately warn of the hazards of prenatal exposure to APAP, which was a direct and proximate cause of Plaintiffs’ injuries and associated damages.

STATEMENT OF PARTIES

3. At all material times, Plaintiffs have been citizens and residents of Antioch, California, and the United States. Plaintiffs are currently citizens and residents of Mountain House, California, and the United States.

4. CVS is incorporated in Rhode Island, with its principal place of business also in Rhode Island.

5. Costco is incorporated in Washington, with its principal place of business also in Washington.

6. Defendants are multinational companies involved in the research, development, testing, manufacture, labeling, production, marketing, promotion, and/or sale of APAP through their over-the-counter store brands (hereinafter, the “Store Brand APAP”).

7. Defendants are individually, and jointly and severally liable to Plaintiffs for damages they suffered, arising from Defendants' design, manufacture, marketing, labeling, distribution, sale, and placement of the defective Store Brand APAP into the market, effectuated directly and indirectly through their agents, servants, employees, and/or owners, all acting within the course and scope of their agencies, services, employments, and/or ownership.

8. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all material times acting on behalf of Wal-Mart and within the scope of their employment or agency.

VENUE AND JURISDICTION

9. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiffs and Defendants. *See supra* ¶¶ 3–5.

10. The amount in controversy exceeds \$75,000.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district.

12. Defendants have and continue to conduct substantial business in the State of California and in this District, distribute the Store Brand APAP in this District, receive substantial compensation and profits from sales of the Store Brand APAP in this District, and have made material omissions and misrepresentations and breaches of warranties in this District, so as to subject Defendants to in personam jurisdiction in this District.

13. Defendants are registered to transact business in California.

14. This matter is properly assigned to the San Francisco or Oakland Division of this District pursuant to Civil Local Rules 3-2(c) and 3-2(d) because Defendants maintain retail stores in Contra Costa County and other counties within the San Francisco or Oakland Division, and Plaintiffs reside in Contra Costa County. Therefore, because Defendants maintain retail stores in Sonoma County, a substantial part of the events or omissions that give rise to the claims occurred within this Division within the meaning of Civil Local Rule 3-2(c), and are properly assigned to this Division pursuant to Civil Local Rule 3-2(d).

FACTS COMMON TO ALL COUNTS

**APAP Is Marketed as the Safe Pain Reliever for Pregnant Women,
but APAP Can Cause Neurodevelopment Disorders in Children, such as ASD**

15. APAP was initially discovered in the late 1800's.

16. APAP is sold in billions of units annually in North America alone.

17. APAP is widely used by pregnant women to relieve pain during the term of their pregnancy.

18. APAP was introduced to the US market in 1955 as the first aspirin-free pain reliever.

19. APAP has long been marketed as the safest, and the only appropriate, over-the-counter pain relief drug on the market for pregnant women.

20. More than 65% of women in the United States use APAP during pregnancy.

21. Based upon information and belief, a majority of women who use APAP during pregnancy do so electively for the treatment of headaches, muscle pain, back pain, and infection.

22. These pregnant women electively choose to take APAP because Defendants have marketed APAP as a safe pain reliever for pregnant women.

23. However, increasing experimental and epidemiological research shows that prenatal exposure to APAP alters fetal development, which significantly increases the risks of neurodevelopmental disorders, including but not limited to, ASD.

24. Undisturbed development of the human brain in utero is vital to the health and wellness of a child's development. The human brain is vulnerable and extremely sensitive in utero.

25. During this sensitive time-period in utero, certain chemicals have been found to cause permanent brain injury at low exposure levels.

26. Once ingested by the mother, APAP is known to readily cross the placenta and blood-brain barrier.

27. ASD is a serious neurological and developmental disorder that affects how people interact with others, communicate, learn, and behave.

1 28. There are three functional levels of ASD, with Level 1 requiring support with
2 activities of daily living, Level 2 requiring substantial support with activities of daily living, and
3 Level 3 requiring very substantial support with activities of daily living.

4 29. Treatments for ASD include behavioral management therapy, cognitive behavior
5 therapy, joint attention therapies, medications, occupational therapy, physical therapy, social skill
6 training, and speech-language therapy. Treatment for ASD lasts a lifetime, as there is no cure.

7 30. In or around 2018, the Center for Disease Control and Prevention (“CDC”) found
8 that 1 in 44 (2.3%) 8-year-old children have been diagnosed with ASD.

9 31. This represents an increase from a prior CDC finding that 1 in 68 U.S. children
10 born in 2002 have ASD, which already represented a more than a 100% increase compared with
11 children born a decade prior.

12 32. Parental awareness and changes in diagnoses do not account for the rapid rise in
13 these diagnoses of neurodevelopmental disorders.

14 33. Rather, neurotic exposures, such as prenatal APAP exposure, explain a trending
15 increase in diagnosis.

16 34. For years, the scientific community has published studies showing that prenatal
17 ingestion of APAP can cause ASD.

18 35. For instance, since 2013, there have been six European birth cohort studies,
19 examining over 70,000 mother-child pairs, showing the association between prenatal use of APAP
20 and ASD.

21 36. At this time, the overall body of scientific evidence shows that prenatal use of
22 APAP can cause ASD in the child.

23 37. During all relevant times herein, Defendants were engaged in the business of
24 manufacturing and selling the APAP Products in the United States, and the weight of the scientific
25 evidence available showed prenatal exposure to APAP significantly increases the risk of
26 neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited
27 to ASD.
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1 38. The scientific evidence regarding the risks of in utero exposure of APAP was
2 available to Defendants, and Defendants knew or should have known that prenatal use of APAP
3 can cause ASD.

4 39. Based on information and belief, Defendants have concealed the prenatal APAP
5 exposure-neurodevelopmental link from consumers, like Plaintiff Mother, in part by not reporting
6 the link to the FDA, which relies on drug manufacturers to bring new information about a drug to
7 the agency's attention.

8 40. Moreover, despite knowing that prenatal use of APAP can cause ASD, Defendants
9 continue to market the Store Brand APAP as the safe pain reliever for pregnant women, making
10 mothers believe they are choosing a safe drug for even minor aches, pains, and headaches.

11 **Plaintiff Mother Took Store Brand APAP while Pregnant,**
12 **and It Caused ASD in Plaintiff Child**

13 41. Plaintiff Mother began using the Store Brand APAP in or around June 2017, when
14 she was pregnant with Plaintiff Child, through March 2018, when Plaintiff Child was born.

15 42. During the first and third trimesters of Plaintiff Mother's pregnancy, she took the
16 Store Brand APAP multiple times per week to treat headaches and back pain.

17 43. Plaintiff Mother associated these headaches and back pain with her pregnancy.

18 44. Plaintiff Mother purchased and took the Store Brand APAP in Contra Costa
19 County, California.

20 45. Plaintiff Mother electively took the Store Brand APAP while pregnant.

21 46. Plaintiff Mother believed it was safe for her to take the Store Brand APAP during
22 her pregnancy.

23 47. There is no warning on the Store Brand APAP labels specifically addressing the
24 risks of a child developing ASD if a mother ingests APAP while pregnant.

25 48. Had Plaintiff Mother known of the risk of taking APAP while pregnant, specifically
26 that it could cause ASD in her child, she would not have taken the Store Brand APAP.

27 49. Plaintiff Child was born on March 21, 2018.

1 50. Plaintiff Mother started to have concerns about Plaintiff Child's development when
2 he was about one year old.

3 51. Plaintiff Child was diagnosed with ASD when he was around three years old.

4 52. Plaintiff Child has behavioral issues because of his ASD.

5 53. For instance, Plaintiff Child is extremely emotional and harms himself.

6 54. Plaintiff Child requires constant supervision because of his ASD.

7 55. Plaintiff Mother works multiple jobs to support Plaintiff Child's needs relating to
8 his ASD.

9 56. These issues have a huge impact on Plaintiff Mother, Plaintiff Child, and their
10 family.

11 57. Plaintiff Child's ASD has placed an incredible mental, physical, emotional, and
12 financial strain on Plaintiff Mother.

13 **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

14 58. Due to Defendants' acts of fraudulent concealment, Defendants are estopped from
15 relying on any statutes of limitations or repose. Such acts include Defendants' intentional
16 concealment from Plaintiff Mother and the general public that APAP is defective when there is
17 prenatal exposure, while continuing to market the Store Brand APAP with the adverse effects
18 described in this Complaint.

19 59. Given Defendants' affirmative actions of concealment by failing to disclose
20 information about the defects known to them but not the public—information over which
21 Defendants had exclusive control—and because Plaintiff Mother could not reasonably have known
22 that the Store Brand APAP was defective, Defendants are estopped from relying on any statutes
23 of limitations that might otherwise be applicable to the claims asserted in this Complaint.

24 **COUNT I: STRICT LIABILITY – FAILURE TO WARN**

25 60. Plaintiffs incorporate by reference the allegations in all prior paragraphs.
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1 61. At the time of Plaintiffs' injuries, the Store Brand APAP was defective and
2 unreasonably dangerous to foreseeable consumers, including Plaintiff Mother, because they lacked
3 an adequate warning.

4 62. At all relevant times, Defendants engaged in the business of testing, developing,
5 designing, manufacturing, marketing, labeling, selling, distributing, and promoting the Store
6 Brand APAP, which was defective and unreasonably dangerous to consumers, including Plaintiff
7 Mother, because they did not contain adequate warnings or instructions concerning the dangerous
8 characteristics of ingesting APAP during pregnancy. These actions were under the ultimate
9 control and supervision of Defendants. At all relevant times, Defendants registered, researched,
10 manufactured, distributed, marketed, labeled, promoted, and sold the Store Brand APAP within
11 this District and aimed the marketing at the ultimate consumer. Defendants were at all relevant
12 times involved in the retail and promotion of the Store Brand APAP marketed and sold in this
13 District.

14 63. Defendants had a duty to warn of the risks associated with the use of the Store
15 Brand APAP.

16 64. The Store Brand APAP ingested by Plaintiff Mother during pregnancy was in the
17 same or substantially similar condition as it was when it left possession of the Defendants.

18 65. Defendants expected and intended the Store Brand APAP to reach users such as
19 Plaintiff Mother in the condition in which the Store Brand APAP was sold.

20 66. Plaintiff Mother did not materially alter the Store Brand APAP prior to ingestion.

21 67. Plaintiff Mother ingested the Store Brand APAP as indicated on the Store Brand
22 APAP labels.

23 68. Plaintiff Mother was unaware of the defects and dangers of the Store Brand APAP
24 and was unaware that prenatal exposure increases the risk of brain and behavioral development of
25 children in utero.

26 69. The labels on the Store Brand APAP to consumers lack any warning specific to
27 pregnant women. The information that Defendants did provide or communicate failed to contain
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1 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff
2 Mother to utilize the products safely and with adequate protection, or decide to not ingest the Store
3 Brand APAP at all.

4 70. This alleged failure to warn is not limited to the information contained on the Store
5 Brand APAP's labeling. Defendants were able, in accord with federal law, to comply with relevant
6 state law by disclosing the known risks associated with APAP through other non-labeling
7 mediums, i.e., promotion, advertisements, public service announcements, and/or public
8 information sources. But Defendants did not disclose these known risks through any medium.

9 71. At all relevant times, Defendants had a duty to properly test, develop, design,
10 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, and supply the
11 Store Brand APAP; provide proper warnings for the Store Brand APAP; and take such steps as
12 necessary to ensure the Store Brand APAP did not cause users and consumers, and their children,
13 to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn
14 Plaintiff Mother of dangers associated with APAP. Defendants, as manufacturers, sellers, and/or
15 distributors of pharmaceutical medication, are held to the knowledge of an expert in the field.

16 72. At the time of manufacture, Defendants could have provided the warnings or
17 instructions regarding the full and complete risks of the Store Brand APAP because Defendants
18 knew or should have known of the unreasonable risks of ASD associated with prenatal exposure
19 to and/or the use of such products.

20 73. At all relevant times, Defendants failed and deliberately refused to investigate,
21 study, test, or minimize the dangers to consumers of the Store Brand APAP and to those who
22 would foreseeably use or be harmed by the Store Brand APAP, including Plaintiffs.

23 74. Defendants failed to adequately warn consumers, like Plaintiff Mother, about the
24 significant increased risk of neurodevelopmental disorders in children exposed to APAP
25 prenatally, including but not limited to ASD.

26 75. Defendants failed to adequately inform reasonably foreseeable consumers, like
27 Plaintiff Mother, of the proper usage of the Store Brand APAP.
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1 76. Even though Defendants knew or should have known that APAP posed a grave risk
2 of harm to Plaintiff Child, Defendants failed to exercise reasonable care to warn of the dangerous
3 risks associated with use and prenatal exposure.

4 77. Plaintiff Mother was exposed to the Store Brand APAP without knowledge of their
5 dangerous characteristics.

6 78. At all relevant times, Plaintiff Mother used and/or was exposed to the use of the
7 Store Brand APAP while using them for their intended or reasonably foreseeable purposes, without
8 knowledge of their dangerous characteristics.

9 79. Plaintiff Mother could not have reasonably discovered the defects and risks
10 associated with the Store Brand APAP prior to or at the time of Plaintiff consuming APAP.
11 Plaintiff Mother relied upon the skill, superior knowledge, and judgment of Defendants to know
12 about and disclose serious health risks associated with using the Store Brand APAP.

13 80. If Plaintiff Mother had been properly warned of the defects, dangers, and risks
14 associated with prenatal exposure to APAP, Plaintiff Mother would have decided to not ingest the
15 Store Brand APAP while pregnant.

16 81. Defendants are liable to Plaintiffs for injuries caused by Defendants' negligent or
17 willful failure, as described above, to provide adequate warnings or other relevant information and
18 data regarding the appropriate use of the Store Brand APAP and the risks associated with the use
19 of APAP.

20 82. As a direct and proximate result of Defendants placing defective Store Brand APAP
21 into the stream of commerce, and Plaintiff Mother's ingestion of the Store Brand APAP during
22 pregnancy, Plaintiff Child was exposed to APAP prenatally, causing him to develop ASD.

23 83. As a direct and proximate result of Defendants placing defective Store Brand APAP
24 into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and
25 suffering, emotional distress, lost wages and earning capacity, and diminished quality of life.
26 Plaintiffs respectfully seek all damages to which they may be legally entitled.
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COUNT II: NEGLIGENCE

84. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

85. Although Defendants had a duty to use reasonable care in testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing written instructions and warnings for the Store Brand APAP, Defendants failed to do so.

86. Defendants, directly or indirectly, caused the Store Brand APAP to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff Mother. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, promoted, and sold the Store Brand APAP within this district and aimed at a consumer market within this district.

87. Defendants knew, or in the exercise of reasonable care should have known, that the Store Brand APAP was defectively and unreasonably designed and/or manufactured, and/or marketed, and was unreasonably dangerous and likely to injure persons that were prenatally exposed to them. Defendants knew or should have known that Plaintiff Mother was unaware of the dangers and defects inherent in the Store Brand APAP when she was ingesting them during her pregnancy with Plaintiff Child.

88. At all relevant times, Defendants had a duty to exercise reasonable care in the marketing, advertisement, promotion, and sale of the Store Brand APAP. Defendants' duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using APAP during pregnancy and appropriate, complete, and accurate warnings concerning the potential adverse effects of APAP and, in particular, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

89. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of APAP ingestion while pregnant and, specifically, the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP.

1 90. Defendants failed to provide any kind of warning to pregnant consumers, like
2 Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders
3 in children through prenatal exposure to APAP.

4 91. Accordingly, at all relevant times, Defendants knew or, in the exercise of
5 reasonable care, should have known that use of the Store Brand APAP could cause Plaintiffs'
6 injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products,
7 including Plaintiffs.

8 92. As such, Defendants breached their duty of reasonable care and failed to exercise
9 ordinary care in the design, research, development, manufacture, testing, marketing, labeling,
10 supply, promotion, advertisement, packaging, sale, and distribution of the Store Brand APAP, in
11 that Defendants manufactured and produced defective Store Brand APAP, which carry the
12 significantly increased risk of causing neurodevelopmental disorders in children through prenatal
13 exposure to APAP; knew or had reason to know of the defects inherent in the Store Brand APAP;
14 knew or had reason to know that a user's or consumer's use of the Store Brand APAP created a
15 significant risk of harm and unreasonably dangerous side effects; and failed to prevent or
16 adequately warn of these risks and injuries.

17 93. Defendants had a duty to disclose the truth about the risks associated with APAP
18 in their promotional efforts outside of the context of labeling. Defendants were negligent in their
19 promotion of APAP outside of the labeling context by failing to disclose material risk information
20 as part of their promotion and marketing of the Store Brand APAP, including through the internet,
21 television, and print advertisements.

22 94. Despite Defendants' ability and means to investigate, study, and test the Store
23 Brand APAP and to provide adequate warnings, Defendants failed to do so. Indeed, Defendants
24 wrongfully concealed information and further made false and/or misleading statements concerning
25 the safety and use of APAP.

26 95. Defendants' negligence included:
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- a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the Store Brand APAP while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of APAP and the significantly increased risk of causing neurodevelopmental disorders in children through prenatal exposure to APAP, and, consequently, the risk of serious harm associated with human use of APAP during pregnancy;
- b. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the Store Brand APAP was safe for its intended consumer use and unborn children;
- c. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendants could reasonably foresee would use the Store Brand APAP;
- d. Failing to disclose to Plaintiff Mother, users, consumers, and the general public that use of APAP during pregnancy presents severe risks of neurodevelopmental disorders in children exposed to APAP prenatally;
- e. Failing to warn Plaintiff Mother, users, consumers, and the general public that the Store Brand APAP's risk of harm was unreasonable and that there were safer and effective alternative medications or treatments available to Plaintiff Mother and other users and/or consumers;
- f. Representing that the Store Brand APAP was safe for their intended purposes for pregnant women when, in fact, Defendants knew or should have known the Store Brand APAP was not safe for their intended purposes;
- g. Declining to make or propose any changes to the Store Brand APAP's labeling or other promotional materials that would alert users, consumers, and the general public of the risks of APAP, including to pregnant women;

- h. Advertising, marketing, and recommending the use of the Store Brand APAP, while concealing and failing to disclose or warn of the dangers known by Defendants to be caused by the use of or exposure to APAP;
- i. Continuing to disseminate information to their consumers and the general public, which indicates or implies that the Store Brand APAP is not unsafe for pregnant consumer use; and
- j. Continuing the manufacture and sale of the Store Brand APAP with the knowledge that the Store Brand APAP was unreasonably unsafe and dangerous.

96. Defendants knew and/or should have known that it was foreseeable that children such as Plaintiff Child would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of the Store Brand APAP to consumers, like Plaintiff Mother.

97. Plaintiff Mother did not know the nature and extent of the injuries that could result in her child from the intended use of and/or exposure to APAP prenatally.

98. Defendants' negligence was the proximate cause of Plaintiffs' injuries, i.e., absent Defendants' negligence, Plaintiff Child would not have developed ASD.

99. Defendants' conduct, as described above, was reckless. Defendants regularly risked exposing Plaintiff Mother to the Store Brand APAP while pregnant with Plaintiff Child, with full knowledge of the dangers of the Store Brand APAP and that it could cause ASD in Plaintiff Child. Defendants made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff Mother. Defendants' reckless conduct therefore warrants an award of punitive damages.

100. As a direct and proximate result of Defendants placing the defective Store Brand APAP into the stream of commerce, Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

COUNT III: BREACH OF EXPRESS WARRANTY

101. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

102. At all material times, Defendants manufactured, marketed, sold, distributed, and otherwise placed into the stream of commerce the Store Brand APAP. These actions were under the ultimate control and supervision of Defendants.

103. In advertising, marketing, and promoting the Store Brand APAP to consumers, like Plaintiff Mother, Defendants expressly warranted that the Store Brand APAP was safe for use and reasonably fit for their intended purposes. In advertising, marketing, and otherwise promoting the Store Brand APAP, Defendants intended for pregnant consumers to rely upon their representations regarding safety and fitness, in an effort to induce them to purchase and consume the Store Brand APAP during pregnancy to relieve pain.

104. Defendants expressly warranted to Plaintiff Mother and pregnant consumers that the Store Brand APAP was safe for ingestion during pregnancy.

105. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of the Store Brand APAP, including a duty to:

- a. ensure that the Store Brand APAP did not cause users and their unborn children unreasonably dangerous side effects;
- b. warn of dangerous and potentially incurable side effects; and
- c. disclose adverse material facts, such as the true risks associated with the use of and exposure to APAP during pregnancy, when making representations to users, consumers, and the general public, including Plaintiff Mother.

106. Defendants had the ability to properly disclose the risks associated with APAP usage during pregnancy through multiple channels, not just labeling.

107. At all relevant times, Defendants expressly represented and warranted to the purchasers of the Store Brand APAP, by and through statements made by Defendants in labels, publications, brochures, and other written materials intended for consumers and the general public,

1 that the Store Brand APAP was safe to human health and the environment, effective, fit, and proper
2 for their intended use. Defendants advertised, labeled, marketed, and promoted the Store Brand
3 APAP, representing the quality to consumers and the public in such a way as to induce their
4 purchases or use, thereby making an express warranty that the Store Brand APAP would conform
5 to the representations.

6 108. The representations about the Store Brand APAP, as set forth herein, contained or
7 constituted affirmations of fact or promises made by the seller to the buyer, which related to the
8 goods and became part of the basis of the bargain, creating an express warranty that the goods
9 would conform to the representations.

10 109. Defendants breached express representations and warranties made to Plaintiff
11 Mother, with respect to the Store Brand APAP, including the following:

12 a. Defendants represented through their labeling, advertising, and marketing materials
13 that the Store Brand APAP was safe, and intentionally withheld and concealed
14 information about the risks of serious injury associated with use of APAP and by
15 expressly limiting the risks associated with use within their warnings and labels;
16 and

17 b. Defendants represented that the Store Brand APAP was safe for use and
18 intentionally concealed information that demonstrated that APAP carries the
19 significantly increased risk of causing neurodevelopmental disorders in children
20 through prenatal exposure to APAP, and that the Store Brand APAP, therefore, was
21 not safer than alternatives available on the market.

22 110. Plaintiff Mother detrimentally relied on the express warranties and representations
23 of Defendants concerning the safety and/or risk profile of APAP in deciding to purchase the Store
24 Brand APAP. Plaintiff Mother reasonably relied upon Defendants to disclose known defects,
25 risks, dangers, and side effects of APAP. Plaintiff Mother would not have purchased or used the
26 Store Brand APAP had Defendants properly disclosed the risks associated with the Store Brand
27 APAP, either through advertising, labeling, or any other form of disclosure.
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1 111. Plaintiff Mother had no knowledge of the falsity or incompleteness of Defendants'
2 statements and representations concerning the Store Brand APAP.

3 112. Plaintiff Mother used and/or was exposed to APAP as researched, developed,
4 designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted,
5 sold, or otherwise released into the stream of commerce by Defendants.

6 113. Had the warnings, labels, advertisements, or promotional material for the Store
7 Brand APAP accurately and adequately set forth the true risks associated with the use of such
8 Products, including Plaintiffs' injuries, rather than expressly excluding such information and
9 warranting that the Store Brand APAP was safe for their intended use, Plaintiffs could have
10 avoided the injuries complained of herein.

11 114. As a direct and proximate result of Defendants' breach of express warranty,
12 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost
13 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages
14 to which they may be legally entitled.

15 **COUNT IV: BREACH OF IMPLIED WARRANTY**

16 115. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

17 116. At all material times, Defendants manufactured, marketed, sold, distributed, and
18 otherwise placed the Store Brand APAP into the stream of commerce.

19 117. At all material times, Defendants intended for the Store Brand APAP to be
20 consumed and ingested by pregnant women, like Plaintiff Mother; and Defendants impliedly
21 warranted that the Store Brand APAP and its component parts were of merchantable quality, safe,
22 fit for such use, and adequately tested.

23 118. Defendants were aware that consumers, including Plaintiff Mother, would consume
24 and ingest the Store Brand APAP as directed by the products' labels and promotional materials.
25 Therefore, Plaintiff Mother was a foreseeable user of the Store Brand APAP.
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1 119. But Defendants failed to disclose that APAP has dangerous propensities when used
2 as intended and that use of the Store Brand APAP carries an increased risk of developing severe
3 injuries, including Plaintiff Child's injuries.

4 120. The Store Brand APAP was expected to reach, and did in fact reach consumers,
5 including Plaintiff Mother, without substantial change in the condition in which they were
6 manufactured and sold by Defendants.

7 121. Plaintiff Mother was an intended beneficiary of the implied warranties made by
8 Defendants to purchasers of the Store Brand APAP.

9 122. In reliance upon Defendants' implied warranties, Plaintiff Mother used the Store
10 Brand APAP as indicated, and in the foreseeable manner normally intended, recommended,
11 promoted, and marketed by Defendants.

12 123. Defendants breached their implied warranties to Plaintiffs in that the Store Brand
13 APAP was not of merchantable quality, nor were they safe or fit for their intended use or
14 adequately tested.

15 124. The harm caused by the Store Brand APAP far outweighed their benefit, rendering
16 the Store Brand APAP more dangerous than an ordinary consumer or user would expect and more
17 dangerous than alternative products.

18 125. As a direct and proximate result of Defendants' breach of express warranty,
19 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost
20 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages
21 to which they may be legally entitled.

22 **COUNT V: VIOLATION OF CONSUMER PROTECTION LAWS**

23 126. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

24 127. Plaintiff Mother purchased and used the Store Brand APAP for primarily personal
25 use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of
26 Defendants' actions in violation of the consumer protection laws.

1 128. Had Defendants not engaged in the deceptive conduct described in this Complaint,
2 Plaintiff Mother would not have purchased and/or paid for the Store Brand APAP, and Plaintiffs
3 would not have incurred related injury medical costs.

4 129. Defendants engaged in wrongful conduct while at the same time obtaining under
5 false pretenses moneys from Plaintiff Mother for the Store Brand APAP. Those moneys would
6 not have been paid had Defendants not engaged in unfair and deceptive conduct.

7 130. Defendants engaged in the following unfair methods of competition or deceptive
8 acts or practices, which are proscribed by law:

9 A. representing that goods or services have characteristics, ingredients, uses,
10 benefits, or qualities they do not have;

11 B. advertising goods or services with the intent not to sell them as advertised;
12 and

13 C. engaging in fraudulent or deceptive conduct creating a likelihood of
14 confusion or misunderstanding.

15 131. Plaintiffs were injured by the cumulative nature of Defendants' conduct. The
16 cumulative effect, directed at patients, physicians, and consumers, was to create demand for and
17 sell the Store Brand APAP. Each aspect of Defendants' conduct combined to artificially create
18 sales of the Store Brand APAP.

19 132. Defendants had a statutory duty to refrain from unfair or deceptive acts or trade
20 practices in the design, labeling, development, manufacture, promotion, and sale of the Store
21 Brand APAP.

22 133. Defendants' deceptive, unconscionable, or fraudulent representations and material
23 omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive acts and trade
24 practices in violation of the federal and state consumer protection statutes listed below.

25 134. Defendants' actions, as complained of in this Complaint, constitute unfair
26 competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation
27 of the federal and state consumer protection statutes listed below.

1 135. Defendants have engaged in unfair competition, or unfair or deceptive acts or trade
2 practices, or has made false representations under the following statutes:

- 3 • 15 U.S.C. §§ 2301–12 (1982);
- 4 • Cal. Bus & Prof. Code § 17200, *et seq.* (Unfair Competition Law (“UCL”));
- 5 • Cal. Civ. Code § 17500 (False Advertising Law (“FAL”)); and
- 6 • Cal. Civ. Code § 1750 *et seq.* (Consumer Legal Remedies Act (“CLRA”)).

7 136. To protect consumers against unfair, deceptive, fraudulent, and unconscionable
8 trade and business practices, and false advertising, Defendants, as the suppliers, manufacturers,
9 advertisers, and sellers, are subject to liability under the above legislation enacted against unfair,
10 deceptive, fraudulent, and unconscionable consumer sales practices.

11 137. By knowingly and falsely representing that the Store Brand APAP was fit to be
12 used for the purposes for which they were intended—when in fact they were defective and
13 dangerous—and by other acts alleged, Defendants violated the above statutes, enacted to protect
14 consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices,
15 and false advertising. The UCL prohibits “any unlawful, unfair, or fraudulent business act or
16 practice and unfair, deceptive, untrue, or misleading advertising and any act prohibited by” Section
17 17500 of the California Business and Professions Code. Section 17500, in turn, prohibits any
18 untrue or misleading statements made in connection with the sale of goods. The CLRA defines as
19 statutorily unlawful certain unfair methods of competition and unfair or deceptive practices. Cal.
20 Civ. Code § 1750 *et seq.*

21 138. By knowingly and falsely representing that the Store Brand APAP was fit to be
22 used for the purposes for which they were intended—when in fact they were defective and
23 dangerous when used during pregnancy—and by other acts alleged, Defendants violated the above
24 statutes, enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable
25 trade and business practices, and false advertising.

26 139. Defendants’ actions and omissions are uncured or incurable, deceptive acts under
27 the above legislation.
28

1 140. Defendants had actual knowledge of the defective and dangerous conditions of the
2 Store Brand APAP but failed to take any action to cure such defective and dangerous conditions.

3 141. Plaintiff Mother relied upon Defendants' misrepresentations and omissions in
4 determining which Store Brand APAP (if any) to ingest.

5 142. Defendants' deceptive, unconscionable, or fraudulent representations and material
6 omissions to consumers constituted unfair and deceptive acts and practices.

7 143. By reason of the unlawful acts in which Defendants engaged, and as a direct and
8 proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

9 144. As a direct and proximate result of Defendants' violations of the above-listed
10 legislation, Plaintiffs have sustained economic losses and other damages and are entitled to
11 statutory and compensatory damages in an amount to be proven at trial.

12 **COUNT VI: NEGLIGENT MISREPRESENTATION**

13 145. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

14 146. Defendants had a duty to accurately and truthfully represent to consumers,
15 including Plaintiff Mother, and the public that the Store Brand APAP had not been adequately
16 tested and found to be a safe and effective treatment for pregnant women. Defendants breached
17 that duty as their representations were false.

18 147. Defendants failed to exercise ordinary care in the representations concerning the
19 Store Brand APAP while Defendants were involved in its manufacture, sale, testing, quality
20 assurance, quality control, and distribution in interstate commerce, because Defendants
21 negligently misrepresented the Store Brand APAP's high risk of unreasonable and dangerous
22 adverse side effects.

23 148. Defendants also breached their duty in representing to Plaintiff Mother that the
24 Store Brand APAP had no serious side effects when ingested during pregnancy.

25 149. As a foreseeable, direct, and proximate result of Defendants' negligent
26 misrepresentations, Defendants knew or had reason to know that the Store Brand APAP had been
27 insufficiently tested or had not been tested at all; and that they lacked adequate and accurate
28

1 warnings, and created a high risk, or a higher than acceptable reported and represented risk, of
2 adverse side effects. Those side effects include neurodevelopmental disorders in children, such as
3 ASD.

4 150. As a direct and proximate result of Defendants' breach of express warranty,
5 Plaintiffs have suffered permanent injuries, significant pain and suffering, emotional distress, lost
6 wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages
7 to which they may be legally entitled.

8 **PUNITIVE DAMAGES**

9 151. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

10 152. Defendants failed to adequately test and study the Store Brand APAP to determine
11 and ensure that the Store Brand APAP was safe and effective prior to releasing them for sale for
12 human consumption.

13 153. Further, Defendants continued to manufacture and sell the Store Brand APAP after
14 obtaining knowledge and information that they were defective and unreasonably unsafe in that
15 they did not include adequate warnings.

16 154. Defendants were aware of the probable consequences of the dangerous and
17 defective product, including the risk of neurodevelopmental disorders in children, such as ASD,
18 when they suffered prenatal exposure.

19 155. At all material times, Defendants knew or should have known that the Store Brand
20 APAP was inherently dangerous with respect to the following: the risk of neurodevelopmental
21 disorders in children, such as ASD, when they suffered prenatal exposure; pain and suffering; loss
22 of life's enjoyment; and unsuccessful treatments to cure the conditions proximately related to the
23 use of the Store Brand APAP, as well as the other permanent and lasting severe personal injuries.

24 156. Defendants' misrepresentations included knowingly withholding material
25 information from consumers and the public, including Plaintiff Mother, concerning the safety and
26 efficacy of the Store Brand APAP, which deprived Plaintiff Mother of vitally necessary
27
28

1 information with which to make a fully informed decision about whether to use the Store Brand
2 APAP.

3 157. At all material times, Defendants also knew and recklessly and/or intentionally
4 disregarded the fact that the Store Brand APAP can cause debilitating and life-altering side effects
5 with greater frequency than safer alternative methods, products, and/or treatments. But Defendants
6 recklessly failed to advise the medical community and the general public, including Plaintiff
7 Mother, of that fact.

8 158. At all material times, Defendants intentionally misstated and misrepresented data;
9 and Defendants continue to misrepresent data so as to minimize the perceived risk of injuries and
10 the rate of complications caused by or associated with the Store Brand APAP.

11 159. Notwithstanding the foregoing and the growing body of knowledge and
12 information regarding the true and defective nature of the Store Brand APAP, with its increased
13 risk of side effects and serious complications, Defendants continue to aggressively market the
14 Store Brand APAP to consumers, including the pregnant community at large, without disclosing
15 the true risk of the complications and side effects.

16 160. When Plaintiff Mother consumed the Store Brand APAP and since then,
17 Defendants have known the Store Brand APAP was defective and unreasonably dangerous without
18 an adequate warning. But Defendants continued to manufacture, produce, assemble, market,
19 distribute, and sell the Store Brand APAP to the pregnant community so as to maximize sales and
20 profits at the expense of the health and safety of expecting mothers in a conscious, reckless, and/or
21 intentional disregard of the likely and foreseeable harm caused by the Store Brand APAP to
22 members of the public, including Plaintiffs.

23 161. At all material times, Defendants have concealed and/or failed to disclose to the
24 public the serious risks and the potential complications associated with the Store Brand APAP, so
25 as to ensure continued and increased sales and profits and to the detriment of the public, including
26 Plaintiffs.

162. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiffs to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants individually, and jointly and severally. Plaintiffs also request compensatory damages, punitive damages, or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendants, individually, and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

- i. Compensatory damages to Plaintiffs for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;
- ii. Restitution and disgorgement of Defendants' profits;
- iii. Applicable statutory penalties;
- iv. Punitive or enhanced compensatory damages;
- v. Reasonable attorneys' fees as provided by law;
- vi. Past and future costs of all proceedings;
- vii. All ascertainable economic damages;
- viii. Prejudgment interest on all damages as allowed by law; and
- ix. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands a trial by jury on all issues so triable.

1 Dated: September 23, 2022

Respectfully submitted,

2 /s/ Warren D. Postman

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